



The 2009 Influenza A(H1N1) “Swine Flu” Outbreak: An Overview

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Summary

On April 29, 2009, in response to the global spread of a new strain of influenza, the World Health Organization (WHO) raised its influenza ("flu") pandemic alert level to Phase 5, one level below declaring that a global influenza pandemic was underway. According to WHO, "the declaration of Phase 5 is a strong signal that a pandemic is imminent and that the time to finalize the organization, communication, and implementation of the planned mitigation measures is short."

In hindsight, officials now believe the outbreak began as clusters of severe respiratory illness in Mexico in March 2009, or perhaps earlier. The novel flu virus was first identified in two children in Southern California in late April 2009. Health officials quickly confirmed that many of the illnesses in Mexico involved the same new flu strain. Since then, a growing number of single or clustered cases of illness have been identified across the United States, Canada, and several other countries. As of May 5, 2009, 1,124 cases meeting the WHO criteria for confirmation have been confirmed in 21 countries in North America, Europe, Asia, and Oceania. These include more than 400 U.S. cases, as well as cases in multiple states in Mexico and provinces in Canada. The majority of the WHO confirmed cases are in Mexico, the United States, and Canada.

Investigations to date suggest that human infections with the new flu strain are usually mild, although severe illnesses and deaths have been reported. This pattern is similar to the behavior of seasonal flu, which circulates the globe each year. Health officials continue to monitor the situation, noting that the efficiency of viral transmission and the severity of illness could change.

The new flu strain was initially dubbed "swine flu" because it contains genetic material from flu strains that normally circulate in swine. But there has been no evidence to date that pigs are involved in the transmission of this virus to humans. There have been concerns that the term "swine flu" has had unwarranted trade implications for swine and pork products. On April 30, 2009, WHO began referring to the new strain as influenza A(H1N1). On May 2, the Canadian Food Inspection Agency (CFIA) reported finding the outbreak strain in a swine herd in Alberta, the first time the strain has been identified in swine. Preliminary investigation suggests that the herd was exposed to the virus from a Canadian who had recently returned from Mexico and had been exhibiting flu-like symptoms.

Federal agencies have adopted a pandemic response posture under the overall coordination of the Secretary of Homeland Security. Among other things, officials have released antiviral drugs from the national stockpile, and efforts to develop a vaccine are underway. The Obama Administration has requested \$1.5 billion in emergency supplemental appropriations to address the threat, and congressional committees in both chambers have convened hearings to assess the situation.

This report provides an overview of key actions taken and authorities invoked by WHO and the U.S. government. First, it discusses the WHO process to determine the phase of a threatened or emerging flu pandemic and touches on a number of related issues. The report then examines actions taken by the Departments of Homeland Security and Health and Human Services and provides information about appropriations and funding for pandemic flu activities. Finally, the report summarizes U.S. government pandemic flu planning documents and lists sources for additional information about the situation as it unfolds. This report will be continually updated to reflect unfolding events.

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Introduction

On April 29, 2009, in response to the global spread of a new strain of influenza ("flu"), the World Health Organization (WHO) raised its influenza pandemic alert level to Phase 5, one level below declaring that a global influenza pandemic was underway. According to WHO, "the declaration of Phase 5 is a strong signal that a pandemic is imminent and that the time to finalize the organization, communication, and implementation of the planned mitigation measures is short."¹

In hindsight, officials believe the outbreak began as clusters of respiratory illness in Mexico in March 2009, or perhaps earlier. The novel flu virus was first identified in two children in Southern California in late April 2009. Health officials quickly confirmed that many of the illnesses in Mexico involved the same new flu strain. Since then, a growing number of single or clustered cases of illness have been identified across the United States, Canada, and several other countries. As of May 5, 2009, 1,124 cases meeting the WHO criteria for confirmation have been confirmed in 21 countries in North America, Europe, Asia, and Oceania. These include more than 400 U.S. cases, as well as cases in multiple states in Mexico and provinces in Canada.

H1N1 Influenza Outbreak: Status as of May 5, 2009

International: World Health Organization (WHO)

<http://www.who.int/csr/disease/swineflu/en/index.html>

- WHO's pandemic flu alert level is at Phase 5 (i.e., community-level outbreaks in two or more countries in one WHO region); countries are urged to activate their pandemic preparedness plans. Phase 6, the highest level, indicates a global pandemic.
- WHO reports a total of 1,124 confirmed cases in 21 countries around the world. Mexico has 590 confirmed cases including 25 deaths.
- WHO advises no restriction of regular travel or closure of borders; however, sick individuals are advised to delay travel. No infection risk from consumption of well-cooked pork products.

United States: Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA) <http://www.cdc.gov/h1n1flu>; <http://www.fda.gov/h1n1flu>

- CDC reports a total of 403 confirmed cases in 38 states, including one death in Texas.
- Federal officials declared a public health emergency on April 26.
- CDC has released to states 11 million treatment courses of the antiviral drugs Tamiflu and Relenza, and sent an additional 400,000 courses to Mexico.
- FDA has issued Emergency Use Authorizations for certain unapproved uses of Tamiflu and Relenza, and for use of an unapproved diagnostic test for the new H1N1 strain.
- CDC has issued mitigation guidance for the general public; specific guidance for clinicians, laboratories, and pregnant women; and recommendations for H1N1-affected schools and communities. CDC has recommended against non-essential travel to Mexico.
- Federal government and manufacturers are developing a vaccine against the new H1N1 strain.

¹ World Health Organization (WHO), *Pandemic Influenza Preparedness and Response: A WHO Guidance Document*, April 2009, p. 32, <http://www.who.int/csr/disease/influenza/pipguidance2009/en/index.html>.

The new influenza strain responsible for the outbreak is an apparent reassortment of several existing strains of influenza A subtype H1N1 virus, including strains typically found in pigs, birds, and humans (see box below). The U.S. Centers for Disease Control and Prevention (CDC) reports that the symptoms and transmission of the novel H1N1 flu from person to person are much like that of seasonal flu. Laboratory testing of the new strain indicates that the antiviral drugs oseltamivir (Tamiflu) and zanamivir (Relenza) are expected, in most cases, to be effective in treating illnesses that result from this new strain.

In response to the situation, Janet Napolitano, Secretary of the Department of Homeland Security (DHS), has assumed the role of Principal Federal Official, coordinating federal response efforts, and Charles E. Johnson, then the Acting Secretary of Health and Human Services (HHS), declared a public health emergency. Among other things, that declaration authorized the Food and Drug Administration (FDA) to issue Emergency Use Authorizations (EUAs), permitting certain unapproved uses of Tamiflu and Relenza (such as in very young children), as well as the use of an unapproved diagnostic test for the new flu strain, and unapproved uses of certain protective devices such as respirator facemasks.

CDC has released stocks of Tamiflu and Relenza, as well as respiratory protection devices and other medical supplies, from the Strategic National Stockpile (SNS), to help states respond to the outbreak. CDC reports that it has released to state health officials 11 million of the 50 million treatment courses of Tamiflu and Relenza stockpiled in the SNS, and purchased additional courses to replenish the stockpile. CDC also has activated its Emergency Operations Centers to coordinate the agency's response to the outbreak, sent 400,000 treatment courses of antiviral drugs to Mexico, and issued an advisory recommending travelers to postpone all non-essential travel to Mexico.

U.S. border control agents are to visually inspect incoming travelers from Mexico, and refer those who appear to be sick to CDC quarantine stations or local health officials. Administration officials are resisting calls to implement more aggressive measures such as closing the U.S.-Mexico border, noting that the new flu strain is already in the United States and that the focus of mitigation strategies is on where U.S. illnesses are being reported, and on patients' families and their surrounding communities.

In the United States, many affected communities have implemented school closures if students have been found to be infected with the new H1N1 flu strain. The CDC notes:

Children are very susceptible to getting this new virus and schools may serve as amplification point[s] for spread of this new virus in a community. The reason for closing schools during this H1N1 outbreak is to try to reduce the spread of the virus. However, little information is available on what the effectiveness of a school closure might be in preventing further community spread of this new virus. In addition, the risk of severe illness from this virus is not yet clear.²

School closures are challenging for all parties involved. Among other things, parents must find alternate arrangements for care of their children, educators must adopt alternate means of delivering their services, and children's education may be compromised. In an assessment of state

² CDC, *Update on School (K – 12) Dismissal and Childcare Facilities: Interim CDC Guidance in Response to Human Infections with the 2009 Influenza A H1N1 Virus*, May 1, 2009 (continually updated), http://www.cdc.gov/h1n1flu/K12_dismissal.htm.

pandemic flu preparedness conducted by HHS and DHS in 2007 through 2008, planning for school closures was found to be a weakness among the states.³

The U.S. response to the current situation involves a slate of pandemic flu plans that were developed, beginning around 2004, to address concerns about the global spread of a novel strain of influenza, the H5N1 avian flu. In the fall of 2005, Congress provided \$6.1 billion in supplemental appropriations for pandemic planning across several departments and agencies.⁴ These earlier efforts, and others aimed at preparedness for bioterrorism and emerging infections in general, have streamlined the response to the new H1N1 flu. At this time, evidence shows that illnesses caused by the new strain are generally milder than seen with the H5N1 avian flu. Among the many challenges facing government officials during the current response is modulating decisions about the rigor of community mitigation interventions, such as school closures, for an incident that is not, at this time, "worst-case."

Influenza Defined

Influenza ("flu") is a respiratory illness that can be transmitted from person to person. Flu viruses are of two main genetic types: Influenza A and B. Influenza A strains are further identified by two important surface proteins that are responsible for virulence: hemagglutinin (H) and neuraminidase (N).

Seasonal flu circulates each year in the winter in each hemisphere. The dominant flu strains in global circulation change from year to year, but most people have some immunity; infection can be fatal. CDC estimates that there are about 36,000 deaths from seasonal flu each year, on average. Vaccines are made each year based on predictions of the strains that are most likely to circulate in the upcoming flu season.

Avian flu ("bird flu") is caused by viruses that occur naturally among wild birds, and that may also affect domestic poultry. In 1997 a new H5N1 strain of avian flu emerged in Asia, and has since caused millions of deaths among domestic poultry, and hundreds of deaths in humans. Health officials have been concerned that this strain could cause a human pandemic, and governments around the world have carried out a number of preparedness activities, including vaccine development and stockpiling, and planning for continuity of services.

Swine flu occurs naturally and may cause outbreaks among wild and domestic swine. People do not normally get swine flu, but each year CDC identifies a few isolated cases of human flu that are caused by flu strains typically associated with swine.

Pandemic flu is caused when a novel strain of human flu (i.e., one that spreads from person to person) emerges and causes a global outbreak, or pandemic, of serious illness. Because there is little natural immunity, the disease is often more severe than is typical of seasonal flu.

(Adapted from HHS, "Flu Terms Defined," <http://www.pandemicflu.gov>. For more information about pandemic flu, see "Understanding Pandemic Influenza" in CRS Report RL33145, *Pandemic Influenza: Domestic Preparedness Efforts*.)

The Obama Administration has requested \$1.5 billion in emergency supplemental appropriations to address the threat. Congressional committees in both chambers have convened hearings to assess the situation.

The remainder of this report provides some discussion of key actions taken and authorities invoked by WHO and the U.S. government. First, it discusses the WHO process to determine the phase of a threatened or emerging flu pandemic and touches on a number of related issues. The report then examines actions taken by the Departments of Homeland Security and Health and

³ HHS and DHS, *Assessment of States' Operating Plans to Combat Pandemic Influenza: Report to Homeland Security Council*, "Operating Objective B.4—Enhance State Plans to Enable Community Mitigation through Student Dismissal and School Closure," January 2009, pp. 25-26, http://www.pandemicflu.gov/plan/states/state_assessment.html.

⁴ CRS Report RS22576, *Pandemic Influenza: Appropriations for Public Health Preparedness and Response*, by Sarah A. Lister.

Human Services and provides information about appropriations and funding for pandemic flu activities. Finally, the report summarizes U.S. government pandemic flu planning documents and lists sources for additional information about the situation as it unfolds. A brief chronology of the H1N1 flu outbreak is included in an appendix. All dates refer to 2009 unless otherwise specified. This report will be continually updated to reflect unfolding events.

Key Official Actions by WHO

Determination of Influenza Pandemic Phase

The World Health Organization is the coordinating authority for health within the United Nations system. It is responsible for providing leadership, guiding a research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries, and monitoring and assessing health trends. WHO does not have enforcement powers.

An influenza pandemic occurs when a novel flu strain emerges and spreads across the globe, causing serious illness among humans. For that to happen, the virus must have the following three features: it must be genetically novel so that there is a lack of preexisting immunity; it must be pathogenic (i.e., capable of causing illness in humans); and it must be easily transmitted from person to person.

WHO, in consultation with experts in member countries, monitors global movement of flu strains among human populations, and has developed a scale for monitoring pandemic risk. The scale consists of five “pre-pandemic” phases with increasing incidence of animal and then human illness and transmission, and a sixth phase that represents a full-blown human pandemic, with sustained viral transmission and outbreaks in most or all regions of the world. Historically, flu pandemics have occurred in multiple waves before subsiding. **Table 1** describes the phases of a flu pandemic, as defined by WHO.

As a result of the rapid spread of the new H1N1 strain, WHO raised its official pandemic alert level from Phase 3, where it had been for several years because of the threat of H5N1 avian flu, to Phase 4 on April 27, and then to Phase 5 on April 29.⁵ Phase 3 means that a novel flu strain is causing sporadic cases of small clusters of disease but is not sufficiently transmissible to sustain community-level outbreaks. Phase 4, by contrast, signals that human-to-human transmission of the virus is sufficient to sustain community-level outbreaks. According to WHO, raising the alert level to Phase 5 means that there is sustained community-level transmission in two or more countries within one WHO region, and that a pandemic may be imminent. WHO pandemic phases are depicted in graphical form **Figure 1**, which shows that WHO considers Phase 5 as a global call for full-strength pandemic response efforts, to continue throughout a declared Phase 6, were a pandemic to ensue.

Governments have been urged by WHO to develop pandemic influenza preparedness and response plans. Generally these plans are staged according to WHO pandemic phases. Similarly,

⁵ WHO, “Current WHO Phase of Pandemic Alert,” http://www.who.int/csr/disease/avian_influenza/phase/en/index.html.

corporations and other interests have developed comprehensive plans that would unfold according to WHO phase determinations.

In announcing her decision to raise the level of influenza pandemic alert from Phase 4 to Phase 5 on April 29, WHO Director-General Dr. Margaret Chan said:

All countries should immediately activate their pandemic preparedness plans. Countries should remain on high alert for unusual outbreaks of influenza-like illness and severe pneumonia. At this stage, effective and essential measures include heightened surveillance, early detection and treatment of cases, and infection control in all health facilities. This change to a higher phase of alert is a signal to governments, to ministries of health and other ministries, to the pharmaceutical industry and the business community that certain actions should now be undertaken with increased urgency, and at an accelerated pace.⁶

Table 1. WHO Influenza Pandemic Phases

(Current alert level is highlighted)

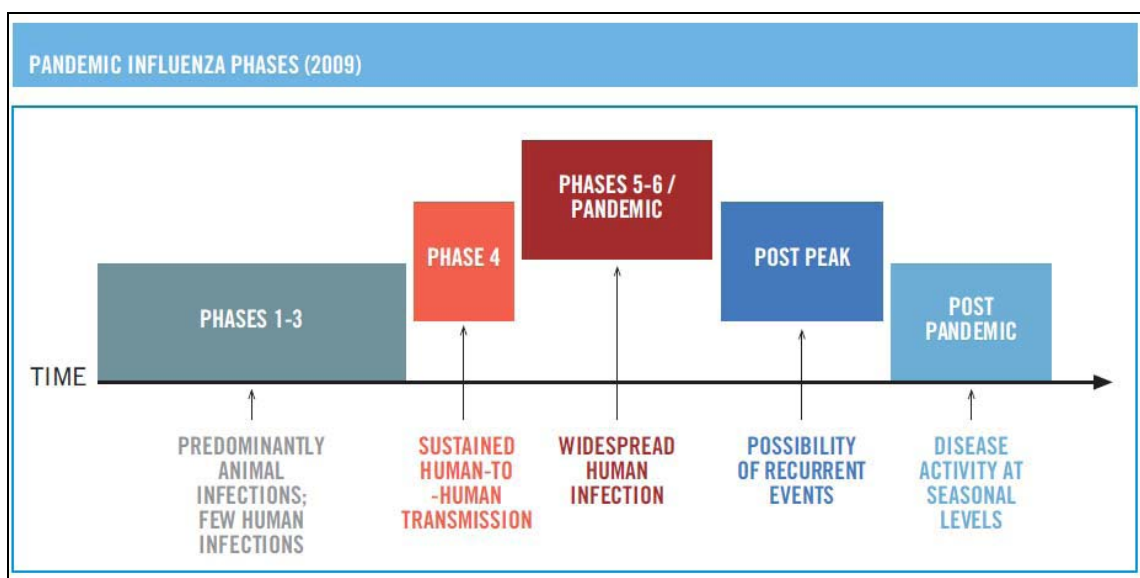
Phase	Description
Phase 1	No animal influenza virus circulating among animals has been reported to cause infection in humans.
Phase 2	An animal influenza virus circulating in domesticated or wild animals is known to have caused infection in humans and is therefore considered a specific potential pandemic threat.
Phase 3	An animal or human-animal influenza reassortant ^a virus has caused sporadic cases of small clusters of disease in people, but has not resulted in human-to-human transmission sufficient to sustain community-level outbreaks.
Phase 4	Human-to-human transmission of an animal or human-animal influenza reassortant ^a virus able to sustain community-level outbreaks has been verified.
Phase 5	The same identified virus has caused sustained community-level outbreaks in two or more countries in one WHO region. ^b
Phase 6	In addition to the criteria defined in Phase 5, the same virus has caused sustained community-level outbreaks in at least one other country in another WHO region. ^b
Post-peak Period	Levels of pandemic influenza in most countries with adequate surveillance have dropped below peak levels.
Possible New Wave	Level of pandemic influenza activity in most countries with adequate surveillance rising again.
Post-pandemic Period	Levels of influenza activity have returned to the levels seen for seasonal influenza in most countries with adequate surveillance.

Source: Adapted from WHO, *Pandemic Influenza Preparedness and Response: A WHO Guidance Document*, April 2009, Table 1, p. 13, <http://www.who.int/csr/disease/influenza/pipguidance2009/en/index.html>.

- a. A reassortant virus results from a genetic reassortment process in which genes from animal and human influenza viruses mix together to create a new strain.
- b. WHO governs through six regional offices that do not strictly correspond with the world's continents. The WHO regions are the African Region; the Region of the Americas; the South-East Asia Region; the European Region; the Eastern Mediterranean Region; and the Western Pacific Region. See "WHO—Its People and Offices," <http://www.who.int/about/structure/en/index.html>.

⁶ WHO, statement by WHO Director-General Dr. Margaret Chan regarding swine influenza, April 29, 2009, http://www.who.int/mediacentre/news/statements/2009/h1n1_20090429/en/index.html.

Figure 1. WHO Influenza Pandemic Phases



Source: WHO, *Pandemic Influenza Preparedness and Response: A WHO Guidance Document*, April 2009, Figure 3, p. 31, <http://www.who.int/csr/disease/influenza/pipguidance2009/en/index.html>.

International Health Regulations

In 2005, the World Health Assembly adopted a revision of the International Health Regulations (IHR), giving a new mandate to WHO and member states to increase their respective roles and responsibilities for the protection of international public health. The IHR(2005) require signatory nations (which include the United States) to notify WHO of all events that may constitute a “Public Health Emergency of International Concern,” and to provide information regarding such events. The IHR(2005) also include provisions regarding designated national points of contact, definitions of core public health capacities, disease control measures such as quarantine and border controls, and others. The IHR(2005) require WHO to recommend, and signatories to use, control measures that are no more restrictive than necessary to achieve the desired level of health protection.⁷

On April 25, 2009, upon the advice of the Emergency Committee called under the rules of the IHR(2005), the WHO Director-General declared the global threat of H1N1 “swine flu” a Public Health Emergency of International Concern. This designation calls upon signatories to provide timely and transparent notification of events to WHO, to collaborate with other countries in disease reporting and control, and to adopt effective risk communication strategies to reduce the potential for international disease spread and the likelihood of unilateral imposition of trade or travel restrictions by other countries.⁸

⁷ For more information, see CRS Report R40560, *The 2009 Influenza A(H1N1) Outbreak: Selected Legal Issues*, coordinated by Kathleen S. Swendiman and Nancy Lee Jones.

⁸ WHO, *International Health Regulations*, <http://www.who.int/ihr/en/>.

Travel Guidance

A number of governments have instituted enhanced passenger screening practices at their borders, and policymakers have debated more extensive prohibitions against the entry of travelers from countries or areas affected by the outbreak. The WHO has consistently advised against movement restrictions as a means to control influenza, citing a lack of evidence of their effectiveness, coupled with their potentially harmful effects on public confidence, local economies, and trade.⁹

Food Safety Guidance

WHO has published a joint statement with Food and Agriculture Organization of the United Nations (FAO), the World Organization for Animal Health (known by its French acronym, OIE), and the World Trade Organization (WTO), saying:

In light of the spread of influenza A(H1N1), and the rising concerns about the possibility of this virus being found in pigs and the safety of pork and pork products, we stress that pork and pork products, handled in accordance with good hygienic practices recommended by the WHO, FAO, Codex Alimentarius Commission and the OIE, will not be a source of infection.

To date there is no evidence that the virus is transmitted by food. There is currently therefore no justification in the OIE Terrestrial Animal Health Standards Code for the imposition of trade measures on the importation of pigs or their products.¹⁰

Key U.S. Government Actions

Department of Homeland Security (DHS)

Leadership Designation

On April 27, Janet Napolitano, Secretary of the Department of Homeland Security (DHS), stated in a press briefing that she was serving as the coordinator of the federal response to the flu outbreak, having assumed the role of Principal Federal Official (PFO).¹¹ According to the National Response Framework (NRF), which guides a coordinated federal response to disasters and emergencies in general, the Secretary of Homeland Security leads federal incident response.¹²

⁹ WHO, *No Rationale for Travel Restrictions*, May 1, 2009, http://www.who.int/csr/disease/swineflu/guidance/public_health/travel_advice/en/index.html.

¹⁰ *Joint FAO, OIE, WHO and WTO Statement on A(H1N1) virus*, May 2, 2009, http://www.wto.org/english/news_e/news09_e/jt_stat_02may09_e.htm.

¹¹ Department of Homeland Security, *Remarks by Secretary Napolitano at Media Briefing on H1N1 Flu Outbreak*, April 27, 2009, <http://www.dhs.gov/ynews/>.

¹² CRS Report RL34758, *The National Response Framework: Overview and Possible Issues for Congress*, by Bruce R. Lindsay. The PFO position has been controversial, however, because it may conflict with the role of the Federal Coordinating Officer (FCO), a leadership position established in the Robert T. Stafford Disaster Relief and Emergency Assistance Act (the Stafford Act).

Customs and Border Protection (CBP) Activities

Customs and Border Protection (CBP), in DHS, is to monitor incoming travelers at ports of entry (typically a visual inspection for possible symptoms), provide information about disease control measures, and refer symptomatic persons to a CDC quarantine station¹³ or a local public health official for evaluation. According to CBP, "at this time all U.S. ports of entry are open and operating as normal with officers using risk based border screening."¹⁴

Administration officials are resisting calls to implement more aggressive measures such as closing the U.S.-Mexico border, noting that the new flu strain is already in the United States and that the focus of mitigation strategies is on where U.S. illnesses are being reported, and on patients' families and their surrounding communities. WHO and CDC officials have commented that scientific evidence does not support closure of a border to travelers as an effective means of controlling the spread of influenza.¹⁵

Department of Health and Human Services (HHS)

Determination of a Public Health Emergency

On April 26, Charles E. Johnson, then the Acting HHS Secretary, who is responsible for coordinating the public health and medical response to the flu outbreak, declared a public health emergency pursuant to Section 319 of the Public Health Service Act.¹⁶ Among other things, this authority enables FDA to implement an authority in the Federal Food, Drug, and Cosmetic Act—the so-called Emergency Use Authorization (discussed below)—allowing for the use of unapproved medical treatments and tests, under specified conditions, if needed during an incident.

FDA: Emergency Use Authorization

If an emerging public health threat is identified for which no licensed or approved product exists, the Federal Food, Drug and Cosmetic Act authorizes the FDA Commissioner to issue an Emergency Use Authorization (EUA) so that unapproved but potentially helpful countermeasures can be used to protect the public health.¹⁷ On April 27, pursuant to authority provided by the prior public health emergency determination, FDA issued EUAs to allow emergency use of (1) oseltamivir (Tamiflu) and zanamivir (Relenza) for the treatment and prophylaxis of influenza; (2)

¹³ CDC, *Quarantine Stations*, http://www.cdc.gov/ncidod/dq/quarantine_stations.htm.

¹⁴ U.S. Customs and Border Protection, *CBP Monitors H1N1 Flu Outbreak; All Ports Operating Routinely*, April 30, 2009, <http://www.cbp.gov/xp/cgov/newsroom/alerts/flu/>.

¹⁵ Donald G. McNeil, "Containing Flu Is Not Feasible, Specialists Say," *The New York Times*, April 29, 2009. See also WHO, *No Rationale for Travel Restrictions*, May 1, 2009, http://www.who.int/csr/disease/swineflu/guidance/public_health/travel_advice/en/index.html.

¹⁶ HHS, "HHS Declares Public Health Emergency for Swine Flu," press release, April 26, 2009, <http://www.hhs.gov/news>. More information about this authority is available in CRS Report RL33579, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, by Sarah A. Lister, and CRS Report R40560, *The 2009 Influenza A(H1N1) Outbreak: Selected Legal Issues*, coordinated by Kathleen S. Swendiman and Nancy Lee Jones.

¹⁷ Food and Drug Administration, *Guidance: Emergency Use Authorization of Medical Products*, July 2007, <http://www.fda.gov/oc/guidance/emergencyuse.html>.

disposable respirators for use by the general public; and (3) an unapproved diagnostic test for the new flu strain.¹⁸

CDC: Travel Notices

On April 27, CDC issued a Travel Health Warning, its highest advisory level, recommending that U.S. travelers avoid all nonessential travel to Mexico.¹⁹ (The agency had issued a Travel Health Precaution, the next lower advisory level, on April 25.) On April 28, the Department of State issued a travel alert to U.S. citizens of the health risks of travel to Mexico due to the flu outbreak, noting the CDC's Travel Health Warning of the previous day.²⁰ These advisories regarding travelers leaving the United States are voluntary.

Naming the Virus Strain

When news of the outbreak of a new flu strain emerged, WHO, CDC, and others referred to the virus as H1N1 "swine influenza" or "swine-origin influenza." This is based on the presumed evolutionary origin of the strain from strains that circulate in swine, since it contains genetic material typically found in North American and Eurasian swine flu strains. There has been no evidence to date that pigs are involved in the transmission of this virus to humans, however. There have been concerns that the term "swine flu" has had unwarranted economic and trade implications for swine and pork products, among other concerns. Others have raised concerns that because of religious practices that call for the avoidance of swine and pork products by some persons of Jewish or Muslim faiths, disease control measures may be compromised in these groups if illness is perceived as a social stigma. On April 29, 2009, officials from HHS, DHS, and other federal agencies referred to the virus as "2009 H1N1."²¹ On April 30, 2009, WHO began referring to the new strain as influenza A(H1N1).

On May 2, the Canadian Food Inspection Agency reported finding the H1N1 outbreak strain in a swine herd in Alberta, the first time the strain has been identified in swine. Preliminary investigation suggests that the herd was exposed to the virus from a Canadian worker who had recently returned from Mexico and had been exhibiting flu-like symptoms when he worked in proximity to the swine.²²

¹⁸ Information is available at CDC, "Swine Flu: Emergency Use Authorization (EUA) of Medical Products and Devices," <http://www.cdc.gov/swineflu/eua/>, and FDA, "2009 H1N1 (Swine) Flu Virus," <http://www.fda.gov/h1n1flu/>.

¹⁹ CDC, *Travel Health Warning: Travel Warning: Swine Influenza and Severe Cases of Respiratory Illness in Mexico—Avoid Nonessential Travel to Mexico*, April 27, 2009, <http://www.cdc.gov/travel/content/SwineFluMexico.aspx>.

²⁰ U.S. Department of State, Bureau of Consular Affairs, *Travel Alert: Mexico - 2009-H1N1 Influenza*, April 28, 2009, http://travel.state.gov/travel/cis_pa_tw/pa/pa_3028.html.

²¹ See, for example, HHS, "Secretary of Health and Human Services Kathleen Sebelius Holds News Conference on Swine Flu," transcript, comments of Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases, National Institutes of Health, April 29, 2009.

²² Canadian Food Inspection Agency, "An Alberta Swine Herd Investigated for H1N1 Flu Virus," press release, May 2, 2009, <http://www.inspection.gc.ca/english/toce.shtml>.

Appropriations and Funding

Public Health Emergency Funding Mechanisms

For the response to a public health incident the HHS Secretary may, under certain conditions, use two designated emergency funds, discussed below. Neither has received a prior appropriation, however, so the Secretary is not currently able to use these funding mechanisms for the response to the H1N1 flu outbreak.

The first mechanism is a no-year "Public Health Emergency Fund," which becomes available to the HHS Secretary upon the determination of a public health emergency pursuant to Section 319 of the Public Health Service Act. This authority was invoked with respect to the H1N1 flu outbreak on April 26. (See the earlier section "Determination of a Public Health Emergency.")²³ The other mechanism is the "Covered Countermeasure Process Fund," which would be used to provide compensation to individuals for serious physical injuries or deaths from the use of medical countermeasures, as identified in a declaration issued by the HHS Secretary.

Emergency Supplemental Appropriations for FY2009²⁴

On April 27, Representative Obey, Chairman of the House Appropriations Committee, and Senator Harkin, Chairman of the Senate Labor, Health and Human Services, Education, and Related Agencies Appropriations Subcommittee, both suggested that Congress might add funds to the pending FY2009 spring supplemental appropriations request to respond to the H1N1 flu outbreak.²⁵ On April 30, President Obama sent a letter to House Speaker Nancy Pelosi requesting \$1.5 billion for this purpose, in funds to remain available until expended. The request did not include specific line items, but rather asked broadly for the funds to address certain activities, namely, supplementing antiviral stockpiles; developing a vaccine; supporting monitoring, diagnostic, and public health response capabilities; and assisting international efforts to stem this outbreak and to address related international needs.²⁶ The President requested that funds be provided to a new account, "Unanticipated Needs for Influenza," in the Executive Office of the President, to be available for transfer, including to the Departments of Agriculture, HHS, DHS, and State, the U.S. Agency for International Development (USAID), and others, upon congressional notification.

State and local health officials have reported recent staff losses in health departments across the nation as a result of the economic downturn.²⁷ They are seeking \$1.035 billion in the FY2009 spring supplemental appropriation to stabilize their workforces, purchase stockpiles of antiviral

²³ For more information, see "Federal Funding to Support an ESF-8 Response," in CRS Report RL33579, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, by Sarah A. Lister.

²⁴ CRS Report R40531, *FY2009 Spring Supplemental Appropriations for Overseas Contingency Operations*, coordinated by Stephen Daggett and Susan B. Epstein.

²⁵ Rob Margetta, "Harkin, Obey Want Swine Flu Funds in Supplemental," *CQ Today*, April 27, 2009.

²⁶ Executive Office of the President, Office of Management and Budget, Estimate #2, 111th Cong., 1st Sess., April 30, 2009, http://www.whitehouse.gov/omb/assets/budget_amendments/supplemental_04_30_09.pdf.

²⁷ Kevin Sack, "Local Health Agencies, Hurt by Cuts, Brace for Flu," *The New York Times*, April 30, 2009.

drugs to treat victims of the outbreak, and purchase antiviral drugs and protective equipment for their own workers and other responders within their jurisdictions.²⁸

Prior Funding for Pandemic Flu Preparedness

In the fall of 2005, in the aftermath of Hurricane Katrina, and as H5N1 avian flu was spreading across several continents, Congress provided \$6.1 billion in supplemental appropriations for pandemic planning across several federal departments and agencies.²⁹ Since then, annual funding has been provided to CDC, FDA, and for other activities in HHS to continue work on vaccine development, stockpiling of countermeasures, and assistance to states. The U.S. Departments of Agriculture and the Interior have also received annual funding to monitor avian flu in domestic poultry and wild birds, respectively, and USAID has received funds to assist other countries in managing avian flu transmission to humans, and preparing for a possible pandemic.³⁰

HHS has tracked influenza spending in its annual budget requests for the past several fiscal years, using comparable criteria from year to year. These amounts are presented in the Department's annual budget requests, in sections designated for pandemic influenza.³¹

As noted above, Congress has provided targeted appropriations for influenza activities, including pandemic preparedness, vaccine capacity for seasonal flu, avian flu surveillance in domestic poultry and wildlife, international assistance, and related matters. Congress is also interested in how agencies budget for influenza within their existing activities, in addition to those amounts specified by Congress. The amount that an agency or department budgets for influenza is of interest, but defining such an amount is difficult, for two reasons.

First, for about 15 years, domestic public health capacity for infectious disease control has moved away from "categorical" funding and programs (i.e., one disease at a time), and toward the development of flexible capacity that can adapt to new, unanticipated threats. These flexible surveillance systems, laboratory networks, communications platforms, and other capabilities, can pivot rapidly to address new threats. But because pandemic planning efforts are tightly woven into the fabric of these flexible capabilities, it is not easy to tease out threads that describe the nation's investment solely for influenza. Any attempt at this requires making judgments about what is "in" and "out" of scope that are somewhat arbitrary. Second, for similar reasons, it can be difficult to tease apart investments made for pandemic flu, versus seasonal flu, versus avian or swine flu, versus investments in drug and vaccine development in general. Because different agencies use different methods and assumptions to account for their influenza spending, these amounts are not necessarily comparable between agencies, and caution is advised in adding such amounts together as if they were comparable.

²⁸ National Association of County and City Health Officials (NACCHO), Association of State and Territorial Health Officials (ASTHO), and Trust for America's Health (TFAH), "H1N1 Influenza Response Emergency Supplemental Appropriations Request," April 2009, <http://www.naccho.org/advocacy/index.cfm>.

²⁹ CRS Report RS22576, *Pandemic Influenza: Appropriations for Public Health Preparedness and Response*, by Sarah A. Lister.

³⁰ Information can be found in CRS Reports on the applicable appropriations bills, at http://apps.crs.gov/cli/level_2.aspx?PRDS_CLI_ITEM_ID=73, and: CRS Report R40239, *Centers for Disease Control and Prevention Global Health Programs: FY2004-FY2009*; and CRS Report RS22913, *Global Health: Appropriations to USAID Programs from FY2001 through FY2009*, both by Tiaji Salaam-Blyther.

³¹ See HHS Budgets in Brief for FY2004 through FY2009 at <http://www.hhs.gov/budget/>.

U.S. Pandemic Influenza Preparedness Documents

In the George W. Bush Administration, pandemic flu preparedness efforts were coordinated by the Homeland Security Council.³² Numerous federal and other documents that are specific to preparedness and response for a flu pandemic have been published. Selected documents are listed below. These plans are intended to address a pandemic caused by any so-designated flu strain, but they were written when there was significant global concern about H5N1 avian flu. To date, that flu strain has behaved quite differently from the current H1N1 outbreak strain. In particular, the H5N1 strain has not shown the ability to transmit efficiently from person to person, but human infections that result directly from contact with infected poultry have generally been very severe, and there has been a high fatality rate.³³

Unless otherwise noted, the U.S. pandemic flu plans below can be found on a government-wide pandemic flu website managed by HHS.³⁴

- The *National Strategy for Pandemic Influenza*, November 2005, published by the Homeland Security Council, outlines general responsibilities of individuals, industry, state and local governments, and the federal government in preparing for and responding to a pandemic.
- *National Strategy for Pandemic Influenza, Implementation Plan*, May 2006, published by the Homeland Security Council, assigns more than 300 preparedness and response tasks to departments and agencies across the federal government; includes measures of progress and timelines for implementation; provides initial guidance for state, local, and tribal entities, businesses, schools and universities, communities, and non-governmental organizations on the development of institutional plans; provides initial preparedness guidance for individuals and families. One- and two-year implementation status reports have also been published.
- The *HHS Pandemic Influenza Plan*, November 2005, provides guidance to national, state and local policy makers and health departments, outlining key roles and responsibilities during a pandemic and specifying preparedness needs and opportunities. This plan emphasizes specific preparedness efforts in the public health and health care sectors.
- The *HHS Pandemic Influenza Implementation Plan, Part I*, November 2006, discusses department-wide activities: disease surveillance; public health interventions; medical response; vaccines, antiviral drugs, diagnostic tests, and

³² Incident preparedness and response are different functions. At each level of government, they involve different leadership roles, legal authorities, organizational structures, and funding mechanisms. Generally, during an incident, certain conditions must be met before a jurisdiction can implement response activities, or access funds reserved for that purpose. With respect to the current H1N1 flu outbreak, the U.S. federal government has commenced pandemic flu response activities, under the overall coordination of the Secretary of Homeland Security.

³³ For more information about H5N1 avian flu and related public health concerns, see WHO, *Avian influenza*, http://www.who.int/csr/disease/avian_influenza/en/index.html; WHO, *Confirmed Human Cases of Avian Influenza A(H5N1)*, http://www.who.int/csr/disease/avian_influenza/country/en/; and CRS Report RL33145, *Pandemic Influenza: Domestic Preparedness Efforts*, by Sarah A. Lister (archived).

³⁴ See <http://www.pandemicflu.gov/plan/federal/index.html>.

- personal protective equipment (PPE); communications; and state and local preparedness.
- *Department of Defense Implementation Plan for Pandemic Influenza*, August 2006, provides policy and guidance for the following priorities: (1) force health protection and readiness; (2) the continuity of essential functions and services; (3) Defense support to civil authorities (i.e., federal, state, and local governments); (4) effective communications; and (5) support to international partners.
 - *VA Pandemic Influenza Plan*, March 2006, provides policy and instructions for Department of Veterans Affairs (VA) in protecting its staff and the veterans it serves, maintaining operations, cooperating with other organizations, and communicating with stakeholders.
 - *Pandemic Influenza Preparedness, Response, and Recovery Guide for Critical Infrastructure and Key Resources*, published by DHS, September 2006, provides business planners with guidance to assure continuity during a pandemic for facilities comprising critical infrastructure sectors (e.g., energy and telecommunications) and key resources (e.g., dams and nuclear power plants).
 - *State pandemic plans*: All states were required to develop and submit specific plans for pandemic flu preparedness, as a requirement of grants provided by HHS.³⁵

Key Information Sources

CRS Reports and Experts

2009 H1N1 "Swine Flu": CRS Experts: <http://www.crs.gov/experts/WE04022.shtml>

Current CRS Reports on public health and emergency preparedness in general:
http://apps.crs.gov/cli/cli.aspx?PRDS_CLI_ITEM_ID=3276&from=3&fromId=13

Current CRS Reports on specific aspects of the pandemic influenza threat:

- CRS Report R40560, *The 2009 Influenza A(H1N1) Outbreak: Selected Legal Issues*, coordinated by Kathleen S. Swendiman and Nancy Lee Jones.
- CRS Report RL32724, *Mexico-U.S. Relations: Issues for Congress*, by Mark P. Sullivan and June S. Beittel.
- CRS Report R40531, *FY2009 Spring Supplemental Appropriations for Overseas Contingency Operations*, coordinated by Stephen Daggett and Susan B. Epstein.

³⁵ For more information, see HHS, *Assessment of States' Operating Plans to Combat Pandemic Influenza: Report to Homeland Security Council*, January 2009, at <http://www.pandemicflu.gov/plan/states/index.html>, and CRS Report RL34190, *Pandemic Influenza: An Analysis of State Preparedness and Response Plans*, by Sarah A. Lister and Holly Stockdale.

- CRS Report RL34724, *Would an Influenza Pandemic Qualify as a Major Disaster Under the Stafford Act?*, by Edward C. Liu.
- CRS Report RL33381, *The Americans with Disabilities Act (ADA): Allocation of Scarce Medical Resources During a Pandemic*, by Nancy Lee Jones.
- CRS Report RS22327, *Pandemic Flu and Medical Biodefense Countermeasure Liability Limitation*, by Henry Cohen and Vanessa K. Burrows.
- CRS Report RL33609, *Quarantine and Isolation: Selected Legal Issues Relating to Employment*, by Nancy Lee Jones and Jon O. Shimabukuro.
- CRS Report RS21507, *Project BioShield: Purposes and Authorities*, by Frank Gottron.
- CRS Report RL31873, *Banking and Financial Infrastructure Continuity*, by N. Eric Weiss.
- CRS Report RS22264, *Federal Employees: Human Resources Management Flexibilities in Emergency Situations*, by Barbara L. Schwemle.

Archived CRS Reports on the threat of pandemic influenza: These products generally discuss concerns about a possible human flu pandemic resulting from H5N1 avian influenza, and enhanced federal preparedness efforts during 2005 through 2007.

- CRS Report RL33145, *Pandemic Influenza: Domestic Preparedness Efforts*, by Sarah A. Lister.
- CRS Report RL33219, *U.S. and International Responses to the Global Spread of Avian Flu: Issues for Congress*, by Tiaji Salaam-Blyther.
- CRS Report RS22576, *Pandemic Influenza: Appropriations for Public Health Preparedness and Response*, by Sarah A. Lister.

World Health Organization (WHO) Information

- Information about the current H1N1 swine flu situation: <http://www.who.int/csr/disease/swineflu/en/index.html>.
- Pandemic Influenza Preparedness and Response: A WHO Guidance Document, (April 2009): <http://www.who.int/csr/disease/influenza/pipguidance2009/en/index.html>.
- Current phase of flu pandemic alert: http://www.who.int/csr/disease/avian_influenza/phase/en/index.html
- Pan American Health Organization (PAHO), a regional office of the WHO, H1N1 flu page: http://new.paho.org/hq/index.php?option=com_content&task=blogcategory&id=805&Itemid=569
- International Health Regulations (2005): http://www.who.int/topics/international_health_regulations/en/

U.S. Federal Government Information

- DHS, "Department Response to H1N1 (Swine) Flu," with links to information in other federal departments and agencies: <http://www.dhs.gov/xprepresp/programs/swine-flu.shtm>
- CDC, H1N1 (swine flu) page: <http://www.cdc.gov/swineflu/investigation.htm>
- FDA, 2009 H1N1 (Swine) Flu Virus, <http://www.fda.gov/oc/opacom/hottopics/H1N1Flu/>
- Pandemic flu planning information: <http://www.pandemicflu.gov/> (Note: much of this information is in the context of planning for the H5N1 avian flu threat.)
- HHS Pandemic Planning Updates, addressing monitoring and surveillance, vaccines, antiviral medications, state and local preparedness, and communications, through January 2009: <http://www.pandemicflu.gov/plan/federal/index.html#hhs> (Note: much of this information is in the context of planning for the H5N1 avian flu threat.)

Additional Information

- Mexico, Ministry of Health (in Spanish): <http://portal.salud.gob.mx/>.
- Canada: Public Health Agency of Canada: http://www.phac-aspc.gc.ca/alert-alerte/swine_200904-eng.php; Canadian Food Inspection Agency: <http://www.inspection.gc.ca/english/toce.shtml>.
- Security and Prosperity Partnership of North America, *North American Plan for Avian and Pandemic Influenza*, August 2007, [http://www.spp-psp.gc.ca/eic/site/spp-psp.nsf/vwapj/pandemic-influenza.pdf/\\$FILE/pandemic-influenza.pdf](http://www.spp-psp.gc.ca/eic/site/spp-psp.nsf/vwapj/pandemic-influenza.pdf/$FILE/pandemic-influenza.pdf).
- Center for Infectious Disease Research and Policy (CIDRAP), at the University of Minnesota, frequent updates, including scientific and technical information, <http://www.cidrap.umn.edu/cidrap/content/influenza/swineflu/index.html>.
- Centers for Law and the Public's Health: A Collaborative at Johns Hopkins and Georgetown Universities, H1N1 (Swine Flu) Legal Preparedness and Response page: includes updates of "U.S. Federal, State, or Local Declarations of Emergency or Public Health Emergency," <http://www.publichealthlaw.net/Projects/swinefluphl.php>.

Appendix. Brief Chronology of H1N1 Outbreak³⁶

April 21

- CDC reports that two children in California recently recovered from apparently unrelated infections with a unique strain of influenza A/H1N1 containing gene segments from swine flu viruses. The children had not had contact with pigs, raising concerns about possible human-to-human transmission, and putting health authorities on alert.

April 23

- CDC reports five more U.S. "swine flu" cases, three in California and two in Texas, bringing the total to seven. Most cases experienced mild symptoms and all recovered. The agency determines that the novel flu strain is susceptible to the antivirals Tamiflu and Relenza.

April 24

- CDC reports one additional U.S. "swine flu" case in California, bringing the total to eight, and announces that samples from the deadly outbreak in Mexico match the novel A/H1N1 strain isolated from patients in the United States, who had milder illnesses.
- WHO announces that Mexican officials have reported three separate outbreaks of illness involving hundreds of individuals and including several dozen fatalities. WHO reports that the virus has primarily struck otherwise healthy young adults rather than the very young and old, who typically are affected by seasonal flu.

April 26

- Federal officials declare a public health emergency in response to the outbreak, as CDC announces nine more cases, bringing the U.S. total to 20 cases in five states. Eleven million treatment courses of Tamiflu and Relenza are released from the Strategic National Stockpile, along with personal protective equipment and other medical supplies. CDC releases guidance on facemask and respirator use and recommendations for clinicians and others managing flu outbreaks.

April 27

- CDC confirms 20 more "swine flu" cases, all connected to previous cases at a New York City high school, bringing the U.S. total to 40 cases. Federal officials recommend that people avoid non-essential travel to Mexico. FDA issues Emergency Use Authorizations permitting certain unapproved uses of Tamiflu and Relenza (such as in very young children), as well as the use of an unapproved molecular diagnostic test for the new flu strain.

³⁶ All of the dates refer to 2009. Compiled from websites of the World Health Organization (WHO), <http://www.who.int/csr/disease/swineflu/en/index.html>; Centers for Disease Control and Prevention (CDC), <http://www.cdc.gov/swineflu/>; and Center for Infectious Disease Research and Policy (CIDRAP), <http://www.cidrap.umn.edu/cidrap/content/influenza/swineflu/index.html>.

- WHO raises its pandemic alert level from Phase 3 to Phase 4, having concluded that the novel flu strain is sufficiently transmissible from person to person to sustain community-level outbreaks. European Union officials warn against non-essential travel to areas where outbreaks have been detected.

April 28

- CDC reports a total of 64 confirmed U.S. cases of "swine flu" in five states, saying that it is becoming increasingly clear that the virus is spreading beyond people who recently traveled to Mexico where the outbreak appears to have originated. The Obama Administration asks Congress for a \$1.5 billion supplemental appropriation to combat the outbreak.
- In addition to the U.S. cases, WHO reports a total of 41 confirmed cases in the following six countries: Mexico (26, including seven deaths), Canada (6), New Zealand (3), United Kingdom (2), Israel (2), and Spain (2).

April 29

- CDC reports a total of 91 confirmed U.S. cases in 10 states and confirms the first U.S. "swine flu" death, in a young child in Texas.
- WHO raises its pandemic alert level from Phase 4 to Phase 5 (i.e., evidence of sustained community-level outbreaks in multiple countries) and, in addition to the U.S. cases, reports a total of 57 confirmed cases in the following eight countries: Mexico (26, including seven deaths), Austria (1), Canada (13), Germany (3), Israel (2), New Zealand (3), Spain (4), and the United Kingdom (5).

April 30

- CDC reports a total of 109 confirmed U.S. cases in 19 states, including the one death in Texas. HHS Secretary Sebelius announces that the federal government is sending 400,000 treatment courses of antiviral drugs to Mexico, and purchasing an additional 13 million treatment courses to replenish the Strategic National Stockpile.
- WHO begins referring to the new strain and "influenza A(H1N1)." In addition to the confirmed U.S. cases, WHO reports a total of 148 confirmed cases in the following 10 countries: Mexico; Austria; Canada; Germany; Israel; Netherlands; New Zealand; Spain; Switzerland; and the United Kingdom.

May 1

- The CDC reports a total of 141 confirmed U.S. cases, including the one death in Texas.
- In addition to the confirmed U.S. cases, WHO reports a total of 224 confirmed cases in the following 12 countries: Mexico; Austria; Canada; China, Hong Kong; Denmark; Germany; Israel; Netherlands; New Zealand; Spain; Switzerland; and the United Kingdom.

May 2

- The CDC reports a total of 160 confirmed U.S. cases in 21 states, including the one death in Texas.
- In addition to the confirmed U.S. cases, WHO reports a total of 498 confirmed cases in the following 15 countries: Mexico; Austria; Canada; China, Hong Kong; Costa Rica; Denmark; France; Germany; Israel; Netherlands; New Zealand; Republic of Korea; Spain; Switzerland; and the United Kingdom.

May 3

- The CDC reports a total of 226 confirmed U.S. cases, including the one death in Texas.
- In addition to the confirmed U.S. cases, WHO reports a total of 672 confirmed cases in the following 17 countries: Mexico; Austria; Canada; China, Hong Kong; Costa Rica; Denmark; France; Germany; Ireland; Israel; Italy; Netherlands; New Zealand; Republic of Korea; Spain; Switzerland; and the United Kingdom.

May 4

- The CDC reports a total of 279 confirmed U.S. cases in 36 states, including the one death in Texas.
- In addition to the confirmed U.S. cases, WHO reports a total of 799 confirmed cases in the following 20 countries: Mexico; Austria; Canada; China, Hong Kong; Colombia; Costa Rica; Denmark; El Salvador; France; Germany; Ireland; Israel; Italy; Netherlands; New Zealand; Portugal; Republic of Korea; Spain; Switzerland; and the United Kingdom.

May 5

- The CDC reports a total of 403 confirmed U.S. cases in 38 states, including the one death in Texas.
- In addition to the confirmed U.S. cases, WHO reports a total of 838 confirmed cases in the following 20 countries: Mexico; Austria; Canada; China, Hong Kong; Colombia; Costa Rica; Denmark; El Salvador; France; Germany; Ireland; Israel; Italy; Netherlands; New Zealand; Portugal; Republic of Korea; Spain; Switzerland; and the United Kingdom.

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